

**GUIDANCE DOCUMENT 110-36  
COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING**

§54.1-3410.2 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF, the USP Pharmacists' Pharmacopeia (available beginning Summer 2005), and USP DI Volume III. Some individual chapters, such as 797, may be purchased individually. More information may be found at [www.usp.org](http://www.usp.org) under "Products". In accordance with 18VAC110-20-170, the Board requires any pharmacy engaging in compounding activities to maintain a current reference containing the USP standards relating to compounding, preferably the USP Pharmacists' Pharmacopeia as it contains the specific information relating to pharmacy compounding to include common compounding monographs, standards on containers (Chapters 661 and 671), and several advisory chapters on packaging, compounding and pharmacy calculations, to include Chapters 1136, 1146, 1178, 1150, 1075, and 1160.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. The Board expects that the requirements of Chapter 795 will be found in compliance at time of inspection.

USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The board recognizes that some pharmacies are not currently compliant with the new physical requirements of Chapter 797 and is also cognizant of the time and costs associated with making the necessary capital improvements to facilities in order to comply with these new requirements. Therefore, the Board will allow pharmacies some time to make these improvements. However, the Board does expect at least compliance with the "old" standard of performing sterile compounding in at least a Class 100 (ISO 5) environment. The Board also expects pharmacies to be in compliance with policies and procedures, training and evaluation of personnel and the other requirements of Chapter 797 at the time of inspection.

Normally when an inspector cites a deficiency during an inspection, the pharmacy has 14 days to correct that deficiency and provide a response to the board as to the corrective action taken. If a pharmacy engaging in sterile compounding is cited for non-compliance with the new physical standards of USP Chapter 797, the board will allow the pharmacy 90 days to submit a plan of action to correct the deficiency within 2 years of the date of inspection. However, the Board's expectation is that all pharmacies engaged in sterile compounding be in compliance no later than June 30, 2008.

**Because of the changes to USP 797 that were published December 2007 and became effective June 1, 2008, the Board will allow a one-time extension until October 31, 2008 for pharmacies to comply with the physical standards provisions. After this date, the Board will begin enforcing the physical standards provisions, and non-compliance may result in a monetary penalty of not more than \$5000 per violation. Each sterile preparation that is compounded under conditions not in conformity with §54.1-3410.2, and by reference USP 797, may constitute a single violation.**

*June 8, 2004*

*Revised: June 5, 2006*

*Revised: June 4, 2008*